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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,790	09/15/2000	Mark Chandler	215063.02301	2090

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PATENT ADMINSTRATOR
KATTEN MUCHIN ZAVIS ROSENMAN
525 WEST MONROE STREET
SUITE 1600
CHICAGO, IL 60661-3693

EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 02/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/662,790

Applicant(s)

CHANDLER ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 8-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,6,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 8-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 9.

Claims 1-7 are currently pending.

Specification Objections

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See, for example, pages 15 and 16.

Claims Objections

Claim 7 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 1 and 7 are directed to the same Test Panel. The insertion of “kit” in the preamble does not change the structural or functional limitations of these claims.

Claim Rejections - 35 USC § 112

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 requires that one subset of microspheres be distinguishable from another subset, however, it is not clear as to how the microspheres would be distinguished. Does the distinction refer only to fluorescent intensity or to intensity and color or does it refer to microsphere size or another factor?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by McHugh (Methods in Cell Biology 1994, Chapter 33, Vol.42, pages 575-595).

McHugh describes a technique known as flow microsphere immunoassay for the simultaneous quantitation of several analytes in a sample. He describes in detail the construction of the microsphere panel for this assay. In particular, as in claim 1, the different microsphere classes are coated with different capture reagents and the fluorescence associated with each microsphere class is quantitated with the flow cytometer (page 576, lines 2-4). The use of different microsphere classes, each coated with a different capture reagent, allows for the rapid and simultaneous detection of multiple analytes, as required by claim 1. McHugh also describes that most studies have used 10⁵ to 10⁶ microspheres per reaction mixture. The number of microspheres is dependent upon the assay parameters and enough microspheres must be

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collected to allow gating of single or to separate **distinct** microsphere classes (subsets) (page 590, lines 14-30).

McHugh also describes the use of fluorescence as a descriptor of the microspheres, such that the microspheres can be separated by different fluorescent emissions at different concentrations (page 578, second paragraph), as required by claims 3 and 4.

Claims 5 and 6 require that at least one reagent comprise a small molecule, natural product, synthetic polymer, peptide, polypeptide, polysaccharide, lipid, nucleic acid, or combination thereof or the predetermined analyte comprise a drug, hormone, antigen, antibody, protein, enzyme, DNA, RNA, or combination thereof. McHugh outlines that various studies have utilized a variety of capture reagents, such as antigens, antibody, receptors, immunoglobulins, oligonucleotides, proteins, DNA etc. (page 576, second paragraph). Furthermore, analytes include antigens, antibodies, proteins, DNA etc., thus meeting the limitations of claims 5 and 6.

Claims 1, 3, and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kettman et al. (Cytometry 1998, Vol.33, pages 234-243).

Kettman et al. teach a method and system for analysis of multiple analytes in a single sample. (see abstract, page 234).

“The vehicle for each separate measurement consists of a set of microspheres identifiable by characteristic fluorophores embedded in the particles. The use of robust bench-top flow cytometers for the analysis of the multiple sets of microspheres is facilitated by hardware and software, which acquire the data from cytometer, classify the microspheres according to sets, and collate measurement information for each set of microspheres in real time. This measurement system can analyze up to 64 analytes in a single sample”.

Kettman et al. therefore meet the limitations of claims 1, 3, and 4-6.

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-7 of this application. Claims 1-7 are drawn to a Multi-Analyte Profile Test Panel. The provisional application 60/153,941, while mentioning the MAP Test Panel, does not provide a detailed description of the Panel such that one could use or make it. Instead, the provisional application is drawn to a computer database for diagnosis.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/19515 (22 April 1999-PTO Form 1449).

WO 99/19515 teaches a population of subsets of dyed beads in batches, each one of them having a predetermined ratio or proportion of two or more fluorescent dyes (page 4, line 14-15). The set, having optically distinct microspheres is useful for simultaneous analysis of a plurality of analytes in the same sample. The reagents and analytes can comprise a myriad of substances, including antibodies and antigens (page 19, example 3).

WO 99/19515 also states: " due to a significant improvement over existing methodology is now technically possible to obtain 16-subset, 32-subset, 64-subset or even higher number of bead collections using the instant methodology". Furthermore, a series of analytical reagents could be employed, as in example 3.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

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in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800
AU1631

February 7, 2003

Lori A. Clow, Ph.D.

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Lori A. Clow